REGION 9

QUALITY MANAGEMENT PLAN

U.S. Environmental Protection Agency
Region 9
75 Hawthorne Street
San Francisco, CA 94105

Document Control Number
QA09-008-10-01

January 2003

MANAGEMENT APPROVAL OF REGION 9
DRAFT QUALITY MANAGEMENT PLAN

REGIONAL CONCURRENCES:

Vance Fong
Regional Quality Assurance Manager — January 31, 2003 (Date)

Jane Diamond
Acting Assistant Regional Administrator — 2/7/2003 (Date)

Jack Broadbent
Director, Air Division — 1-9-03 (Date)

Catherine Kuhlman
Acting Director, Water Division — 1/13/03 (Date)

for Enrique Manzanilla
Director, Cross-Media Division — 12/20/02 (Date)

Jeff Scott
Director, Waste Management Division — 01/29/03 (Date)

Keith Takata
Director, Superfund Division — 1-28-03 (Date)

APPROVAL FOR IMPLEMENTATION:

for Wayne Nastri
Regional Administrator — 7 February 2003 (Date)

APPROVAL FOR THE AGENCY:

Nancy Wentworth
Director, Quality Staff — 12 March 2003 (Date)

TABLE OF CONTENTS

SECTION **PAGE**

FOREWORD

The U.S. Environmental Protection Agency (EPA) is authorized to make decisions affecting public health and the environment. With the knowledge that there is an inviolable trust in the Agency, EPA mandated that environmental data collected by and for the Agency be of known quality, and, as appropriate, legally defensible for the decisions to be made with them. The Agency-Wide Quality System, EPA Order 5360.1 A1, EPA Quality Manual for Environmental Programs, May 2000, and EPA Order 5360.1 A2, Policy and Program Requirements for the Mandatory Agency-Wide Quality System, May 2000 (supercedes EPA Order 5360.1, 1984) is this mandate. The Agency-Wide Quality System is intended to ensure that decision makers are provided the necessary knowledge and confidence on which to base their decisions. In accordance with the Order, Quality Management Plans (QMPs) are prepared by each Region to document the Quality System to be implemented for data collection activities conducted in that Region. The Region 9 QMP defines the management and technical activities necessary to plan, implement, assess and ensure the effectiveness of Quality Assurance (QA) and Quality Control (QC) operations applied in the data collection programs. The QMP further establishes the roles, responsibilities, and authorities for implementing the System.

INTRODUCTION

Agency QA Program. Concern over the reliability of data led to the development of an EPA Quality Assurance Program for environmental measurements performed by or for the Agency (EPA Order 5360.1 A1 and A2). In accordance with EPA Order 5360.1 A2, EPA requires that environmental programs be supported by a quality system that complies with the American National Standard Institute/American Society for Quality (ANSI/ASQ) E-4, 1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Technology Programs*, incorporated herein by reference. ANSI/ASQC E4-1994 is a national consensus standard authorized by the ANSI and developed by the ASQ that provides a basis for planning, implementing, documenting, and assessing an effective quality system for collecting and evaluating environmental data for decisions and for use in the design, construction, and operation of environmental technologies. EPA requires conformance to this standard through internal Orders and the Code of Federal Regulations (e.g., 40 CFR 30, 40 CFR 31, 40 CFR 35, 48 CFR 46). All EPA organizational units which perform or support environmental measurements must participate in the Agency QA Program. Contracts, grants and interagency agreements, including State and Tribal programs, are required to address Quality Assurance (QA) as well.

The Quality Staff (QS), under the Assistant Administrator the for Office of Environmental Information [OEI], is the central management authority for the Agency QA Program. The QS develops QA policies and procedures, and oversees the Agency-wide implementation of the Quality Systems in the program offices, Regions, and laboratories.

Regional Quality Management Plan Update. Region 9's participation in the mandatory Agency-Wide Quality System includes preparing a Regional QMP. The QMP prepared by Region 9's QA Office and approved by the QS in 1996 is updated every five years, or more frequently where warranted, to reflect the Quality System implemented in Region 9. The QMP documents the Quality System to be implemented in Region 9 and serves as the 'umbrella' document representing the management and technical activities necessary to plan, implement, assess and ensure the effectiveness of QA and QC operations applied to the data collection programs in Region 9. The QMP also establishes the roles, responsibilities and authorities for implementing Region 9's Quality System. The purpose of the QMP was presented in the foreword and will not be repeated.

The QMP has been revised to conform to QS's "EPA Requirements for Quality Management Plans (QA/R-2)," EPA/240/B-01/002, March 2001, to the extent possible. Where the Agency-wide QA Program previously addressed environmental measurements, the QA/R-2 requirements span pollution control and remediation systems as well, and add quality elements associated with personnel, procurement and computer systems. QA representatives designated by each of the Regional Divisions worked with the Regional QA Manager to update the QMP. Other subject matter specialists in the Region were interviewed to address Sections 4 through 6 of this document which cover Regional and QA activities in Procurement, Records Management, and Computers. This document results from that effort.

SECTION 1
QUALITY MANAGEMENT AND ORGANIZATION

1.1 Regional QA Goals and Policies

The Agency relies on its own environmental measurements and those collected by other Governmental agencies and regulated parties to make decisions affecting public health and the environment. The Agency established the mandatory Agency-Wide Quality System, EPA Order 5360.1 A1 and A2, requiring each Region to establish a structured Quality System to ensure that data of known quality are generated by and for the Agency. The responsibility to implement the system rests with all Regional staff and managers involved in data collection activities. Oversight responsibilities for developing and overseeing the system resides with the QA Office. Having an effective Quality System in place provides decision makers the necessary knowledge and confidence to make the critical decisions for protecting public health and the environment. This Quality System, documented in this QMP, describes the management and technical activities necessary to plan, implement, assess and ensure the effectiveness of QA and QC operations applied to the data collection programs in Region 9. It further defines the roles, responsibilities and authorities for implementing the Region's quality system.

Effective implementation of the Agency-Wide Quality System leads to several benefits, including:

- *Scientific Data Integrity* - EPA will produce data of known and documented quality.

- *Reduced or Justifiable Resource Expenditures* - Resource expenditures can be reduced as EPA's information needs are more closely matched to the information collection activities. For example, through systematic planning, only the appropriate type, amount, and quality of data will be collected by EPA, by others collecting data on behalf of EPA, and by others collecting data to satisfy EPA requirements.

- *Effective Management of Internal and External Activities* - The quality system provides documentation of activities and oversight for evaluation purposes. This reduces the potential for waste, fraud, and abuse.

- *Reliable and Defensible Decisions* - When the quality of data is known, it is possible to determine if the data can be used for a specific decision. This reduces the likelihood of challenges to regulations, enforcement actions, permit appeals, etc., resulting from the use of data of uncertain quality.

Region 9's QA policies and activities regarding environmental data are consistent with the requirements of EPA Order 5360.1 A1 and A2 and other Agency mandates. Basic goals and specific policies are summarized below.

1.1.1. QA Basic Goals

- Environmental data used in decision-making are of known quality.
- Only necessary data are collected.
- Data collected are of the type and quality needed and claimed, and meet established objectives.

1.1.2 QA Policies

The following apply to all Environmental Data Collection Activities (EDCAs) conducted by Agency personnel, its contractors, grant and interagency agreement recipients:

- An appropriate QA planning document (QMP, Quality Assurance Program Plan (QAPrP), Quality Assurance Project Plan (QAPjP), Sampling and Analysis Plan (SAP), Field Sampling Plan (FSP), or Work Plan (WP), etc.) individually or in combination as appropriate, will be developed and approved for each environmental data collection activity prior to the initiation of data collection.
- The intended use(s) and data quality objectives (DQOs) of environmental data will be defined prior to collection of the data, and identified in the appropriate QA planning document and as defined by Agency policies and environmental regulations.
- Regionally approved QA and QC procedures must be funded and integrate into environmental data collection activities.
- Projects and tasks involving environmental data collection will be accomplished in conformance with approved QA planning documents.
- Oversight of data collection activities will be performed and deficiencies or problems promptly corrected.

In accordance with EPA Order 5360.1 A2, a graded approach of QA will be applied to all EDCAs conducted by or for the Agency, and performed throughout all stages of an EDCA:

I. Up-front QA planning occurs during the scoping and planning of the EDCA. Before any work is done, data needs, DQOs, and Quality Assurance/Quality Control (QA/QC) procedures are documented in a QAPrP, QAPjP, SAP, or FSP. The QAPrP, QAPjP, SAP, or FSP is reviewed and approved by the QA Office (QAO) or its authorized EPA

representative. Up-front planning is critical in programs where standard procedures are not defined, or compounds of interest and action levels are not specified by regulations.

II. QA/QC procedures are implemented during the data collection process. Data are acquired according to the methods and procedures documented in the approved QA Planning document. The impact of field and laboratory techniques and sampling and analysis conditions on data quality are determined using field and laboratory QC samples and periodic audits. Oversight and follow-up corrective action are designed to prevent improper procedures from becoming institutionalized.

III. QA review assesses data quality and usability, based on the QA/QC information gathered during data collection. Data validation is used to document and communicate to the data user data quality.

All three stages of QA are important in all EDCAs. The specific QA/QC activities for an EDCA or program, however, are a function of the DQOs. One stage of QA may be emphasized more than others on a given project, and the level of QA may vary from one EDCA to another. Therefore, the Region does not recommend a specific minimum level of QA support for all EDCAs; instead it requires that a level be defined and the decision documented, in a QA planning document.

1.2 Organization and Quality Assurance Responsibilities

1.2.1 Region 9 Program Organization

The Region 9 program organization is shown in Appendix A. Regional management is tiered as follows, in descending order of authority:

Regional Administrator
Division/Office
Section
Team
Staff

The organization charts provided in Appendix A illustrates Region 9's program organization from the Regional Administrator (RA) to the Division level. Subsequent pages identify the Program Offices within the Divisions.

EDCAs are performed in nearly every Division. The QAO provides QA oversight and technical expertise to the Divisions. Program staff are expected to be in conformance with general program and QA guidelines and requirements agreed upon by the QAO, Program

Managers and Division Directors. In addressing the program elements, the direct responsibility for implementation of QA activities is held at the Division and Program level. This is further described in the next section.

1.2.2 Region 9 QA Organization and Responsibilities

Overall responsibility for Quality Assurance (QA) in Region 9 resides with the RA, who is committed to ensure that QA is an identifiable activity with adequate resources allocated for accomplishment of program and Regional goals in the development and execution of all projects and tasks involving environmentally related measurements, both in-house and extramural. The RA's responsibility to QA is outlined in EPA Order 5360.1 A1 (also known as the QA Order) and is specifically addressed in Section 1.2.3 of this QMP.

The responsibility for planning, developing and implementing the Region's Quality System resides with the Regional Quality Assurance Manager (RQAM). The RQAM reports to the Assistant RA (ARA), Policy and Management Division (PMD) (see Appendix A) and is independent of the Divisions responsible for EDCAs. As such, the RQAM is independent from any environmental monitoring management responsibilities, avoiding potential conflict of interest between performing data collection or analysis and quality assuring the data generated by these activities. The dotted line depicted on Region 9 Organization Chart between the RQAM and the Deputy Regional Administrator (DRA) indicates that the RQAM has recourse to elevate issues to the next higher level of senior management, that is, the DRA**.** The RQAM manages the Region's QA employees located in QAO.

The RQAM provides a focal point for implementing and monitoring the Regional QA Program, for technical training, and for auditing the Region's EDCA programs. The RQAM is further responsible for performing overall oversight of the Region's data collection programs. The RQAM interprets, disseminates, and provides direction on successfully implementing Agency policies in the Region. The RQAM balances QA technical assistance and training support to meet the Region's QA needs. Under the direction of the RQAM, QAO employees are responsible for the preparation and implementation of Regional QA policies and guidances, advise the programs on QA matters, review of QA documents and audit of the Region's EDCAs and those of the grantees and IAG recipients. Further responsibilities addressed by the RQAM/QAO are detailed in Section 1.2.4.

The technical assistance and training support provided by the QAO actively supports program Divisions' data collection activities. The Divisions work with the QAO to identify their data quality needs for joint development of the Division's QA program. For example, the Air Division, Base Realignment and Closure, Brownfields, Tribal and Region 9 Laboratory Program work with the QAO to ensure that the QA activities performed in their programs are consistent with Regional and Agency QA guidelines and meet their specific program data quality needs. Program managers and staff, within each Division are responsible for ensuring these QA

activities are implemented successfully. Support is provided the Divisions whenever the need arises, by request to the QAO, or as determined from Management Systems Reviews (MSRs) conducted by the QAO. Effective communication between all levels of staff, management and the RQAM is, therefore, an essential element of QA.

QA assistance for biological monitoring is provided by the Laboratory Program (LP) in PMD. The LP further conducts the Drinking Water Laboratory Certification Program, Discharge Monitoring Report Quality Assurance (DMRQA) laboratory inspections and field audits, and coordinates the Water Supply, Water Pollution, and DMRQA Performance Evaluation Studies.

Based on demonstrated ability to perform QA oversight, the Air Division's Technical Support Office has been authorized by the RQAM to perform QA review and oversight of state and tribal organizations performing EDCAs. The Federal Facilities Cleanup Branch (FFCB), in a signed agreement, is also responsible for performing reviews of QA planning documents. However, they have been provided the flexibility to send more critical projects to the QAO for review. The QAO performs reviews of comments generated by the Air Division Technical Support Office and the FFCB support contractors. While the LP, Air Program, and FFCB perform QA functions, the QAO retains overall oversight responsibility in the Region.

The Region's QA training policy will be implemented. QA101, a basic foundation setting course on QA, is a part of this policy. QA101 is a required training intended to raise awareness, commitment of Regional management and staff involved in EDCAs of their responsibility (i.e., that QA is the responsibility of all – Regional management, staff, grantees and contractors, involved in EDCAs, not just that of the QA Office) to ensure that QA activities are performed and that these activities support their EDCA. The course will build the QA support base and enable staff to perform QA oversight independently or with the assistance from QAO, per Order 5360.1 A2, Section 7.c.5 and 6. The course covers the purpose for having a quality system (generate data of known quality to enable credible, defensible decision making; preserve resources; introduce staff and management of EPA's Quality Management system (QMS) and the Region's Quality Management Plan (QMP) to increase awareness of the Agency and Region's expectation of those responsible for overseeing EDCAs); familiarize management and staff to the components of a quality system and quality management concepts; provide some useful, easy starter tools to perform QA oversight; and how to work with the QA Office. This course will complement other QAO training courses such as Field Sample Plan preparation and soil volatile sample collection.

The RQAM and QAO staff lead the Region and provide guidance in effective QA implementation. RQAM, QAO staff, Division and Program/Project managers involved in data collection are responsible for performing the following:

- Ensure that all applicable **intramural** programs and activities comply fully with the requirements of Order 5360.1 A2

- Ensure that all applicable **extramural** environmental programs for which the manager or staff member is responsible comply fully with the requirements of Order 5360.1 A2

- Assure that the results of environmental programs are of **sufficient quantity and adequate quality** for their intended use.

- Develop **DQOs** for EDCAs.

- Implement and perform oversight of **QA plans**.

- Ensure that proper **sampling and analytical procedures** are used and documented.

- Perform the **day-to-day implementation and oversight** of EDCAs for which they are responsible, including the activities identified in this Section.

- Ensure that **data quality** is determined and known by decision-makers.

- Identify needs for, schedule, and participate in **audits** of data collection and QA procedures.

- Ensure that deficiencies or problems identified through audits are **corrected** expeditiously.

- Ensure that **QA training and technical support needs** are identified and prioritized so that available training resources are used sufficiently.

- **Maintain** approved QAPjPs, FSPs, audit reports, inspection reports, system reviews, corrective action plans, other EDCA related documentation in accordance with Regional Order 2160.

The Environmental Services Assistance Team (ESAT) contractor under the QAO's direction performs sample plan reviews, QA project plan reviews, and data validation. The QAO is responsible for managing this contract and for coordinating their work to meet Regional client's needs.

Section 1.2.3. Regional Administrator/Authorization

The Regional Administrator is responsible for:

- Ensuring that all Regional components and programs comply fully with the requirements of the QA Order and the specifications of the Quality Manual, 5360 A1, including the preparation of a QMP for the Region, implementation of an effective Regional Quality System, and the timely submission of QA Annual Reports and Work Plans (QAARWPs) to OEI;

- Ensuring that quality management is an identified activity with associated resources adequate to accomplish its program goals;

- Ensuring that all applicable environmental programs delegated to State, Tribal and local governments, or performed by organization is outside EPA pursuant to EPA regulations and requirements, comply fully with the requirements of the QA Order;

- Ensuring that quality management and QA/QC training are provided to Regional management and staff;

- Ensuring that Federal agencies and State, Tribal and local governments performing environmental data operations and environmental technology activities under assistance agreements with EPA have sufficient quality management and QA/QC training in order to perform the work successfully;

- Ensuring that periodic management assessments of Regional organizational units performing environmental monitoring programs are conducted to determine the effectiveness of their mandatory Quality Systems; and

- Ensuring that periodic management assessments of State, Tribal, and local governments performing environmental programs are conducted to determine the effectiveness of their mandatory Quality Systems.

1.2.4 Regional QA Managers Responsibilities/Authorization

The RQAM's official responsibilities are identified below. In some cases, the authority and responsibilities are delegated to QAO staff.

- Serves as manager of the Regional QA Program and supervises a group of professional employees providing QA oversight and guidance for the Regional Office. Provide an information focal point for QA and QC concepts and practices.

- Manages the development of the Regional Quality Management Plan and its implementation for all internal and external monitoring and measurement activities.

- Ensures Performance Standards are in place requiring managers and staff to perform specific quality management functions.

- Provides training and guidance on QA programs and policies that are consistent with Agency policies. Ensure that QA training and technical support needs are identified and prioritized so that available training resources are used sufficiently;

- Provides guidance in the development of QAPrPs, QAPjP, SAPs, FSPs or other QA Planning documents for Regional EDCAs as required by the Regional QMP. Reviews and approves (jointly with program managers or project officers (POs)), or designates Program staff and management to review and approve, all plans including those required in State grants, Tribal grants, contracts and cooperative agreements funded by the Agency.

- Prepares QA/QC Requirements and Guidance documents for developing planning documents to enable effective planning, implementation, and assessments of data collection systems

- Manages Contractor Supported Work Assignments, Delivery and Task Orders for QA support contracts, work assignments, delivery orders, and task orders.

- Reviews and approves grant and IAG Documents for QA Requirements to confirm any need for QA requirements, providing any necessary special language or conditions for such QA requirements.

- Reviews and Approves QA planning documents for all projects, contractors, cooperative agreements, and interagency agreements involving data acquisition, data generation, and/or measurement activities that are performed on behalf of EPA.

- Recommend policies and procedures for the management of QA/QC within the Region.

- Review and sign the QA Review Form for contracts.

- Submit periodic reports to Regional management and OEI Quality Staff.

- Arranges laboratory analyses for the data collection programs.

- Coordinates the review and approval of alternate test methods according to the requirements of the Clean Water Act (CWA) program.

- Manages the Regional performance evaluation sample program, used to audit the performance of laboratories in the Region which analyze samples for Agency programs (this differs from the Water Supply, Water Pollution and DMRQA program which are managed by the LP). Interprets the results and oversees corrective action programs.

- Develops and oversees laboratory audit strategies that the QAO utilizes to determine the quality of the work and adherence to established methods, protocols, and QA Plans. Follows up to ensure corrective action is taken.

- Directs the evaluation of analytical data generated by Regional laboratories, including contract laboratories, to determine validity, data quality and usability of data produced for projects.

- Performs management and technical system audits of Regional and State environmental monitoring programs to ascertain effectiveness of QA and QC implementation; ensure that proper QA procedures are used; and that generated data are of the quality needed and claimed. Ensure that deficiencies or problems identified through audits are corrected expeditiously;

- Maintains contact with Headquarters, Regional, State, and Tribal counterparts to promote mutual understanding and coordination in developing and articulating QA requirements.

- Represents the Region or Agency on QA matters as required.

- Addresses disputes or challenges regarding QA. Where a dispute or challenge cannot be satisfactorily addressed by the QAO, the issue is raised to the Assistant Regional Administrator.

As noted earlier in this section, the authority and responsibilities of the RQAM are delegated to QAO staff in some cases. This includes having the ability to elevate issues to the ARA or DRA , if and when situations warrant and necessitate. The process by which QAO staff will access the ARA or DRA is the following: QAOS will have consulted with the RQAM prior

to contacting the ARA or DRA (e.g., a recommendation for corrective action to take place by a specified date is not addressed by the responsible office; the RQAM is not available during the period in which corrective action was to take place; based on the level of risk to the Agency QAO may report the inattention for corrective action to ARA or DRA). Other situations may arise which QAO staff will exercise their best judgement and experience to raise a concern directly, without benefit of consult with the RQAM, to the ARA or DRA (e.g., when the RQAM is not available, QAOS fulfilling the function of the RQAM may elevate a potential risk or vulnerability that they believe needs immediate address to ARA or DRA, as warranted).

1.3 Mandatory Independence of the Regional QA Manager and Provision of Resources to Implement the Quality System

Order 5360.1 A2 requires that the RQAM function independently of programs involved in EDCA and that this individual report to a senior manager having executive leadership authority for the organization. Order 5360.1 A2 further requires that the Office directly responsible for implementing the Region's Quality Systems be provided the authority and necessary resources to carry out the requirements of the Order.

Section 1.2.2, consistent with Order 5360.1 A2, describes the independence of the RQAM. This is subject to change based on forthcoming national policy on RQAM independence. Region 9's RQAM organizational position is expected to be in conformance with this policy, once established.

In addition to the RA allocating resources to support QA functions, discussions are occurring at the national level among the Regional Science and Technology (RS&T) Directors to ensure that all programs involved in EDCAs implement QA and regard it as a priority and necessity for effective decision making. These discussions center on appropriating direct funding for implementing QA in the Regions. This is consistent with the Government Performance Results Act (GPRA) which is meant to track results based on resources and time spent on a function. The reporting requirement is intended to ensure that QA is implemented in EDCAs and that areas of vulnerability are identified and addressed before they become significant problems. Currently, annual reports at the national level that identify Program level QA activities and results are non-existent. The RS&T Directors are working to reverse this condition and to make programs accountable for ensuring QA is addressed in EDCAs they are responsible for.

The RQAM has worked with the ARA to incorporate language in managements performance standards to ensure their support of the Region's QA Program. The standards are commensurate with management responsibilities, as required in EPA Order 5360.1 A2 and 5360 A1, /Quality Manual for Environmental Programs, Section 2.9. Management responsibilities

include provision of support to help assure that: quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as described in the organizations approved QMP, including provision of QA training; performance of Management Systems Review of data collection programs to determine the effectiveness of the quality system; and corrective action is made when deficiencies are identified.

If EDCA related QA disputes arise, the RQAM cooperatively works with the responsible division, office, or organizational unit to resolve them. Where differences cannot be satisfactory addressed by the RQAM, the issue is brought to the ARA's attention for resolution with the responsible party. Follow-up is performed by the RQAM with the ARA to ensure corrective action takes place. If the concern is not addressed despite the support of the ARA, the RQAM will exercise the independent authority discussed in Section 1.2.2 and elevate QA vulnerabilities that place the Region at risk to the DRA and/or RA for resolution. This process is consistent with EPA Order 5360.1 A1, Quality Manual for Environmental Programs, Section 2.8, Dispute Resolution Process.

SECTION 2
QUALITY SYSTEM OVERVIEW

2.1 Environmental Data Collection Activities (EDCAs) Conducted in Region 9

Region 9 has a centralized QA program managed and overseen by the QAO. The EDCAs covered by the Regional QA Program in Region 9 are outlined in Tables 1A-7A (Appendix B) for a specific Division, Branch or program.

2.2 Quality Systems for specific Regional EDCAs

2.2.1. In-House EDCAs. In-house EDCAs are data collection activities which are planned and performed by Regional 9 personnel. In-house activities support a variety of compliance, enforcement, audit and investigation activities, which are listed in Tables 1A-7A. (Activities involving EPA financial assistance or cooperative agreements, which are also listed in Tables 1A-7A, are considered extramural projects.)

An approved QAPrP, QAPjP, SAP, and/or FSP and in some cases, a SOP, is required for all Region 9 in-house activities. Since the documents are sometimes very similar, it is left to the judgment of the QAO staff as to which documents are necessary. Examples are provided below.

- A **continuous data collection activity** is one whose procedures do not change significantly from year to year, such as routine compliance sampling, or monitoring efforts performed under one of the regulatory programs. For this type of data collection activity, one QAPrP which addresses the routine activities may be prepared. The QAPrP should be reviewed annually and revised when significant changes in procedures or organizational responsibilities occur.

- Sometimes QA issues are **site-specific**, such as for a Superfund remedial investigation. Such projects require a QAPjP or SAP for each project, which must be updated if the focus of the project changes significantly. FSPs may also be required, for a project which is completed in phases of sampling. Generally, a SAP is used for discrete one time events which have a distinct starting and ending date, such as a Brownfields investigation, whereas a QAPjP and FSP combination might be used for a more traditional Superfund investigation which may be conducted over several years.

2.2.2. Extramural Projects. Extramural projects involve the expenditure of EPA funds in the form of grants, contracts, or formal cooperative agreements. Region 9's extramural projects that involve EDCAs are identified in Tables 1A-7A and 1B-7B.

The regulations for **financial assistance agreements** (40 CFR, Parts 30, 31, and 35) require applications for financial assistance involving EDCAs to include a QA document in the form of a QA narrative statement, or a QMP. Region 9 does not require that QA Plans be submitted with proposals or with WP in most instances. The QAO also reviews all grant PO decision memoranda (i.e., the memos that authorize the transfer of funds to grantees) for projects involving environmental measurements to determine if the QA requirements are being met. Depending on the nature of the grantee, the type of QA documentation required and the status of the grantee's preparation of that QA documentation, the QAO may place conditions in the grant requiring certain QA documents be prepared before data are collected. The PO and the RQAM are responsible for review and approval of the QA documents, and the language in these grant conditions is mutually agreed upon by the Division and the QAO. The acceptance of the grant by the grantee signifies their agreement to the grant conditions. The responsible project manager ensures that a QA document is prepared and submitted to the Region before environmental measurements take place as part of the financial assistance agreement. Decision memoranda that are exempted from QA Office review are covered in the memorandum entitled: Grant Project Decision Memoranda Exempted from Sign-off by the Quality Assurance Office, March 21, 2000 (Appendix C). This memorandum is effective until it is revised or superceded. Congressional Line Item appropriations are also exempted from QA Office review.

2.2.2.1. Interagency agreements such as with the U.S. Army Corps of Engineers are handled in a similar way to financial assistance agreements, although there are currently no CFR requirements in place concerning QA. The QAO reviews the funding memoranda and inserts appropriate QA conditions. QA documentation prepared by the other agency may be reviewed and approved by the QAO, the funded agency's QA system, or a combination of the two. These types of arrangements are limited to well established Quality Systems. Agreements that are exempted from QA Office review are covered in memorandum: Quality Assurance Requirements for Interagency Agreements (IAGs), October 11, 1996 (Appendix C). This memorandum is effective until it is revised or superceded.

2.2.2.2. The **Contracts** Management Manual (EPA Order 1900.2) and the Procurement Policy Notice (PPN) No. 01-02, "Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions," March 2001) (Appendix D), require that all contract proposals which include environmental measurements be reviewed by the RQAM for adequacy of QA/QC provisions prior to submission to the Contracting Officer. All QA documents incorporated into a contract proposal or required by the contract must be reviewed and approved by the PO and the RQAM prior to the approval or initiation of the project. In addition, if no QA plan is required (i.e., no EDCAs) the PO signs a form that is reviewed by the Contracting Officer.

2.2.2.3. Other extramural projects involving environmental data collection are periodically performed for the Region by other government agencies such as the Department of Defense through formal cooperative agreements, and by parties in the private sector or the regulated community through administrative orders. EPA funds are not directly expended for the data collection activities. Substantial EPA involvement may occur during the performance

of the project, however, and the data may be used by the Agency. The program manager is responsible for the quality of these data, and for incorporating adequate QA/QC provisions into the formal agreement or document initiating the project.

2.3 Requirements and Responsibilities for Implementing Region 9 Quality system

For each EDCA performed in Region 9, the associated QA/QC elements are identified in Tables 1B-7B (Appendix B).

2.4 Quality System Components

2.4.1. Designated Quality Assurance Manager. The Region has a designated RQAM. This individual is the focal point for providing Regional QA direction. Noted in Section 1.2.3 are the RQAM's responsibilities which include communicating and ensuring that the requirements of this QMP are met.

2.4.2. Quality System Documentation. In conformance with the requirements of EPA Order 5360.1 A1 and A2, Policy and Program Requirements for the Mandatory Agency-Wide Quality System, May 2000 and other Agency mandates, this QMP prepared by the QAO, represents Region 9's Quality System. It documents the management practices and principles for ensuring data of known quality are generated by and for the Region. The QMP further describes the roles, responsibilities and authority for implementing Region 9's Quality System. The purpose of Region 9's QMP was already noted in the *Introduction*, and will not be repeated here. With the exception of this QMP, which is reviewed and approved by the OEI's QS, the QAO performs all reviews and approvals of QMPs developed by or for the Region.

QMPs specific to the Region's program offices have been developed by the Laboratory Program, Emergency Response Office, and ESAT Contractor. It is the direction of the Region to work with the Divisions involved in EDCAs to have program specific QMPs in place, whenever appropriate and possible.

2.4.3. Training. QA is everyone's responsibility. Attendance at QA 101 which provides a fundamental understanding of QA and the Regional quality system is required of all staff and managers involved in Environmental Data Collection Activities (EDCAs). Headquarter's (HQ) QS guidance documents form the base of this and all QA training provided in Region 9.

Region specific QA training appropriate to the individual staff or manager's degree of involvement in planning or overseeing EDCA's is also offered by the QAO/QS. These trainings are developed and delivered by QAO staff working with Regional program management and subject matter experts. One-on-one technical assistance is also available to help Divisions

implement QA in their EDCAs. Training is a necessary yet resource-consuming component of the QAO and is generally provided only in response to expressed needs.

2.4.4. Systematic Planning of Projects. The seven step Data Quality Objectives (DQOs) process is the primary systematic planning tool for performing EDCAs, though the Region is flexible in the use of other planning tools, as appropriate. The DQO process is designed to ensure that the type, quantity, and quality of the environmental data collected for use in decision making are appropriate to support specific decisions or regulatory actions. Each step of the DQO process provides a systematic procedure for defining the criteria that a data collection design should satisfy. This includes determining the data quality goals for a project (i.e., what data are needed, why they are needed, how they will be used and who will use them; the tolerable error rate and rigor of QA/QC to be implemented; evaluating alternative data collection and analytical approaches; level of data review, self audits to be performed, corrective actions to be implemented, and resource constraints). The planning process is performed to ensure that the stringency of QA implemented meet the decision making needs of the program.

For some routine monitoring programs and regulatory programs, the National Program Offices have developed or will develop DQOs, usually in the form of regulatory standards. Those DQOs are adopted by the Region's grantees, who are primarily charged with implementing these programs, and incorporated into QAPrPs, QAPjPs, SAPs, and/or FSPs for specific activities, as appropriate. For projects initiated in the Region, the program manager who is responsible for the EDCA is responsible for defining or developing DQOs as part of the planning process. For programs with no defined DQOs, Region 9 encourages the use of the DQO process in the development of the QAPjP.

When DQOs are developed, the use of, "Guidance for the Data Quality Objectives Process for Superfund, Interim Final Guidance," EPA 540/G-93/071, September 1993 is the primary reference document used for the Superfund program. The "Guidance for the Data Quality Objectives Process for Hazardous Waste Sites (G-4HW)," EPA/600/R-00/007, January 2000 and Decision Error Feasibility Trials (DEFT) Software (G-4D), September 1994 are also used, as appropriate. These documents and software guide one through the DQO process in preparation for developing QAPrPs, QAPjPs, and SAPs. Outputs of the DQO process justifying a particular approach to be used in an EDCA are documented in QAPjPs or SAPs following "EPA Requirements for QA Project Plans," (QA/R-5), EPA/240/B-01/003, March 2001.

2.4.5 Providing Guidance on Project Specific Quality Documentation. As noted previously, all EDCAs conducted by Agency personnel, its contractors, grant and interagency agreement recipients are expected to have an appropriate QA planning document. QAO provide guidance on preparing project planning documents directly and indirectly through training, participation in scoping meetings, one-on-one communication, routine document reviews and guidance documents.

QA training on the preparation of QAPrPs, QAPjPs, SAPs, and/or FSPs introduces the audience to the DQO planning process noted above and the elements that need to be addressed in the planning documents. Guidance documents complementing the training are provided to the audience. It is expected that the audience will be able to prepare project specific QA planning documents after receiving training.

QAO staff participate in "scoping" sessions, when requested. Scoping sessions are intended to plan the full scope of an EDCA (i.e., planning, implementation, and assessment), and are essentially a tool used to introduce and educate planners of an EDCA to the site background and problem to be addressed. The strategy to best address the EDCA is then discussed and the DQO process used. Results from this scoping are then documented in a project QA planning document.

QAO or designated QAO EPA authorized personnel performing document reviews often interact directly with planning document authors before, during, and after a planning document is developed. Document reviewers provide project specific and focused assistance, e.g., development of site specific DQO, analytical method selection, sample collection procedures, etc., where necessary. Formal comments are prepared after review of the planning document is completed, identifying areas of QA vulnerability. The QA planning document is then revised to address the comments and resubmitted. This process continues until the planning document is approved.

2.4.6. Data Evaluation. A tiered process has been developed by the QAO for performing data evaluation. The QAO performs these functions as requested by the Divisions, and as resources permit. QAO oversight is provided to EPA contractors when they are to be utilized for performing data review and validation.

The review, validation and evaluation performed by the QAO is based on a 3 tier evaluation system. The rigorousness of data review is successively increased with each tier, based on project specific DQOs and the graded approach. "Graded" means the stringency or rigorousness of the review performed is based on the data quality objectives. For example, the data review performed for a drinking water enforcement investigation may be more stringent than for a routine screening of waste water quality due to the nature of the investigation and the scrutiny it may receive.

Briefly Tier 1A includes a review of the data for gross discrepancies and a review of quality control (QC) data for obvious problems. Tier 1B includes the same approach, but includes a review using the Agency's automated data evaluation software, Computer Aided Data Review and Evaluation (CADRE). Tier 2 includes the same general review, but specific target analytes are targeted for a more in depth review or a full validation based on re-established DQOs. Tier 3 includes a complete validation of all data and analyses. Tier 3 validation is performed in accordance with Superfund "Functional Guidelines for Evaluating Laboratory Data" for CLP organic and inorganic analyses. This guidance is used to validate Superfund data, and is

the basis for the validation procedures for other program data. Appendix F contains the required composition for data packages prepared by non-CLP laboratories for data validated by the Region. Appendix G, January 14, 2000 memo, Documentation of Data Validation Requirements in Quality Assurance Project Plans (QAPjPs), Field Sampling Plans (FSPs) and Sampling and Analysis Plans (SAPs) contains further details on the tiered system.

When performed, data validation consists of an evaluation of the completeness of the documentation of some field and analytical procedures and quality control results, and a comparison of the data quality of the collected data with project DQOs to determine if the DQOs are met. This evaluation and comparison results in the determination that the data met the project specific DQOs, the data use is limited, or the data should be rejected. Data validation results may also be used to determine the need for changes in the design and performance of data collection efforts or in the use and documentation of QC procedures. Problems identified through data validation may also trigger follow-up to address sample collection or laboratory problems, and contractor performance. Once the data are reviewed, the Project Manager is responsible for performing the final determination as to whether the data can be used for the purpose collected. Assistance is provided to the Project Manager by the QAO upon request.

Analytical data generated for Superfund-lead projects through an interagency agreement (IAG) will be reviewed by that supporting agency. The supporting agency should use the Regional Tiered Data Review process to maintain consistency in data review. Similarly, analytical data generated for Superfund-lead projects through a field contract should be reviewed by the primary contractor or an independent sub-contractor. The QAO may conduct system audits of the supporting agency and field contractors to fulfill obligatory oversight responsibilities.

Data review needs from Potentially Responsible Party (PRP)-lead, state-lead, Federal facility-lead, Brownfields-lead, etc. will be met on a case-by-case basis. A memorandum or an e-mail requesting data review must be sent by the project manager to the RQAM.

2.4.7. Document Reviews. Region 9 has a Document Review Team, headed up by a Team Leader, who is responsible for reviewing all QA planning documents. The RQAM and the Team Leader have the responsibility for ensuring that review team members are properly trained in the various document guidances, document reviewers are consistent in the application of these guidances, and reviews share a common format. Reviewers are trained initially by performing parallel reviews with a more senior reviewer until such time it can be demonstrated that they understand how to apply and interpret the appropriate guidance. In addition, the Team Leader performs joint reviews of documents prepared by new reviewers before they are sent out to the RPM or PO, or, in the case of tribes for some grants, directly to the tribe itself. Most reviews by more senior reviewers are peer reviewed by other reviewers prior to being sent to the RQAM for his final sign off. This helps ensure that reviews are of uniform and consistent quality.

During the course of its review, the QAO reviewer assesses whether the document is consistent with national and QA guidance and whether the proposed QA and QC activities that are planned will adequately support the program objectives or DQOs it describes. The review ensures that all aspects of the program are described and that all measurement activities are covered by QA planning. This means that technical and QA activities must agree and jointly support the intended use of the data.

Some, primarily Superfund, documents are sent to the ESAT contractor for review. These reviews are then peer reviewed by a Document Review Team member before sign off by the RQAM. Checklists are also available to assist reviewers, primarily as prompts or reminders.

In the case of QMPs and QAPrPs, where a state, or possibly a tribe, might be defining a QA system which will be used in the future to review and approve QA documents, the QAO must ensure that the system is sufficiently rigorous so that reviews will meet QAO standards. Approval of these plans carries with it an endorsement of the QA system of the organization, and hence, a delegation of responsibility. If the project is part of a block grant for a delegated program or a contract with a state organization, the state will perform the review, subject to its having an approved QA system, otherwise the QAO will perform the review. Delegations are subject to having a QA professional skilled in the performance of QA related responsibilities described in Section 1 of this plan and having an approved QA system in place. Usually if the project or task assignment under a contract is funded directly by EPA, the QAO will perform the review.

The service standard for reviews is 25 days for QA Plans and 14 days for sampling plans, although this may be subject to change depending on a wide variety of factors. These may include, but not be limited to availability of staff, expertise of staff, number of documents requiring review, sampling or other deadlines, and funding available for contractor support.

2.4.8 Management Reviews and Assessments. The standard mechanism for assessing the effectiveness and adequacy of quality assurance measures is an audit. Several types of audits are scheduled and performed throughout the Region by the QAO.

- The management systems review (MSR) evaluates the management of the QA program implemented in the Region and States, i.e., management support, DQOs and planning documents, data quality assessment, audit procedures, and the effectiveness and consistency of corrective actions. A goal of a minimum of one Regional program and one State agency program MSR per year is established. Additional MSRs are scheduled on an as-needed basis, or when problems are identified through other audit pathways.

- A **technical systems audit (TSA)** evaluates aspects of the actual performance of the EDCA, and includes field and laboratory audits. Field audits are scheduled and conducted by the LP staff on an as-needed basis, such as when problems are identified through data validation. QAO staff may assist in the performance of field audits, when needed. Each

Superfund contractor (Remedial Action Contract (RAC), one Superfund Enforcement Support Services (SESS) contract, one Emergency Rapid Remedial Services (ERRS) contract, and one Superfund Technical Assessment & Response Team (START)) and several PRP contractors will be audited once per year. Laboratory audits are performed on Superfund Contract Laboratory Program (CLP) laboratories located within the Region at least once per year and on State, Tribal and Territory drinking water laboratories every three years. The LP and QAO staff also audit laboratories working for Responsible Parties, Federal facilities, Resource Conservation and Recovery Act (RCRA) owner/operators, National Pollution Discharge Elimination System (NPDES) dischargers and the Underground Injection Control program upon request or as needed

- Performance evaluation samples (PES) verifies the ability of a data collection system to produce reliable data on a sample containing known concentrations of specific chemical constituents. The QAO provides single blind (i.e., the laboratory knows that it has received a performance sample) or double blind (i.e., PES are prepared using media that most closely resembles samples being collected from a site (e.g., soil, water) which are made to look like the actual sample and the identity of the PES is unknown to the laboratory performing analyses) audit samples to check laboratory performance for various programs. While this is a very successful program, resources to implement the program are limited. In addition, the LP coordinates the regularly-schedules EPA-wide Water Supply, Water Pollution, and Discharge Monitoring Report QA (DMRQA) PE studies for laboratories which serve various Water programs.

2.4.9. QA Annual Planning. Annual planning for QA is important to ensure that available resources are used to accomplish the most critical QA activities, and that major deadlines are identified. The Region's QA Annual Report and Work plan (QAARWP) is prepared in conjunction with annual QA planning in the Region. It is written by QAO with Regional and State input, and is due to the QS on November 1st of each year. The QAARWP chronicles the QA activities completed, significant highlights and problems, updates to the Regional QMP, and projected activities for the following year.

2.5 Tools for Implementing the Quality System

Many of the principal components discussed above (e.g., Training, Management Systems Reviews, and Data Assessment) are also tools for implementing the quality system in Region 9. These tools along with the documentation requirements, detailed below, enable the effective oversight of the QA implemented in the Region. Using available planning documents, the RQAM is able to measure through MSRs, TSAs and data review the level of understanding and application of QA in the Region thus facilitating effective, prompt corrective action, where necessary. Results from these oversight tools are used for continual quality improvement as described further in Section 10.

2.5.1. Documentation Requirements. All EDCAs conducted by Agency personnel, its contractors, grant and interagency agreement recipients are required to have an appropriate QA planning document (QAPrP, QAPjP, SAP, FSP, or WP, etc.) developed and approved by the QAO or designated QAO EPA authorized personnel for each EDCA prior to the initiation of data collection. Systematic planning such as the DQO process is used to assist in preparing these documents. These documents serve as the basis from which QAO or designated QAO EPA authorized personnel may conduct oversight, ensuring that what is documented is actually implemented.

QAPrPs, QAPjPs, SAPs, FSPs, or WPs are developed in accordance with Regional and national guidance documents which are available from the QAO or QA Web page located at: http://www.epa.gov/region09/qa/r9-qadocs.html. Specific requirements of these documents are highlighted below.

2.5.1.1. Quality Management Plan (QMP). QMPs are generally required to meet the EPA QA requirements for contracts, grants and cooperative agreements. The QMP outlines the structure of an organization's QA program and its underlying QA management policies. The Region uses a graded and flexible approach in the implementation of the QMP requirement. Some of the factors taken into account are the size and nature of the organization, the extent the program is funded by EPA, the organization's QA system, the organizations structure (centralized or decentralized, etc.), and how its work is accomplished (for example, does it use consultants, contracts, grants, in-house staff, etc.). QMPs are prepared using the guidance "EPA Requirements for Quality Management Plans (QA/R-2)," EPA/240/B-01/002, March 2001. In some cases, Region 9 accepts a combination QMP/QA Program Plan to document a organization's quality system. QMPs are submitted to the QAO for review and approval.

In addition to the Regional QMP, the Emergency Response Office developed a QMP, per audit recommendation from the Inspector General (IG). The IG's recommendation was based on the "immediate response" nature of work conducted by the ERO and the need to ensure that work conducted under emergency conditions were also of known and defensible quality. The QMP was reviewed and approved by the QAO. Other program offices are expected to operate in conformance to the Region's QMP.

2.5.1.2. QA Program Plan (QAPrP). Environmental data generation which takes place as part of the implementation of a regulation and which represents a recurring and on-going activity, is considered to be an environmental program. Environmental Programs are implemented by state and tribal partners under grants or cooperative agreements. State and tribal environmental program funded under the Clean Air Act ambient monitoring, Clean Water Act Surface Water Monitoring, and the Resource Conservation and Recovery Act Program are just a few examples of environmental programs. The planning of program-specific data collection activities is documented in QAPrPs. This allows appropriate technical and policy review by EPA and the public of the steps being taken by the program to ensure that data of known quality are generated. When implemented as designed, the QAPrP provides a detailed record of the scope

and objectives of the data collection and QA/QC procedures used. QAPrPs may or may not include elements of a QMP, depending on the size of the organization, the nature of the program, the amount of funding it receives, and how the organization's quality system is structured. QAPrPs are prepared using the QAO's guidance document, "EPA Region 9 Requirements for Quality Assurance Program Plans" (R9QA/03.1), Appendix H, which is adapted from the guidance "EPA Requirements for QA Project Plans," (QA/R-5), EPA/240/B-01/003, March 2001. QAPrPs are expected to define regulatory objectives and criteria for decision making using the data, document requirements for project type activities which often include requirements for preparation of QA Plans or Sampling Plans, provide copies of relevant sampling or other field standard operating procedures (SOPs), include copies of relevant laboratory QA Plans and/or SOPs or Statements of Work, and discuss data reporting and review procedures. QAPrPs are submitted to the QAO for review and approval.

2.5.1.3. QA Project Plan (QAPjP). The planning of project-specific data collection activities is most often documented in QAPjPs. QAPjPs may be prepared by Region 9 staff, contractors, or grantees or their contractors. QAPjPs allow appropriate technical and policy review prior to implementation, and help ensure consistency through the life of a project. When implemented as designed, the QAPjP is a detailed record of the scope and objectives of data collection activities and the procedures and QA/QC used. QAPjPs usually are prepared using the guidance "EPA Requirements for QA Project Plans" (QA/R-5), EPA/240/B-01/003, March 2001, although other formats are acceptable provided that the essential information is covered. QAPjPs may be used to describe program activities being conducted by small programs (e.g., tribes) in lieu of the preparation of a QAPrP. In many cases, Region 9 permits the use of a QAPjP without the preparation of an accompanying Field Sampling Plan provided that sufficient site specific information is provided and sampling SOPs are provided or sampling activities described.

2.5.1.4. Sampling and Analysis Plans (SAPs) are defined by Region 9 as a combination of a QAPjP and a Field Sampling Plan and are considered generally appropriate for one-time sampling events. Their use for multiple sampling activities is permitted on a case by case basis, but is discouraged. Generally these are prepared by small organizations, usually grantees such as tribes or Brownfields recipients whose resources are limited. Although any format is acceptable provided it covers the necessary material, it is expected that most will use the Regions two guidance documents, "Sampling and Analysis Plan (SAP) Guidance and Template Version 1, EPA Analytical Services Used," (R9QA/001.1, April, 2000) and "Sampling and Analysis Plan Guidance and Template, Version 2, Private Analytical Services Used," (R9QA/002.1, April, 2000), Appendix I. SAPs must cover decisions to be made with the data, data quality objectives (DQOs) or regulatory criteria, sampling, analysis, and data review.

2.5.1.5. Field Sample Plan (FSP). Where a QAPjP has been prepared, it may be necessary to describe site specific sampling and analytical procedures that is occurring on a continual basis. A FSP is employed for this purpose. FSPs contain site-specific information, as opposed to project-specific information contained in the QAPjP. FSPs may be required in addition to QAPjPs. FSPs are prepared using guidance "Preparation of a U.S. EPA Region 9

Field Sample Plan for EPA-Lead Superfund Projects" (9QA-05-93, August 1993) and "Preparation of a U.S. EPA Region 9 Field Sample Plan for Private and State Lead Superfund Projects", (9QA-06-93, August 1993) (Appendix J) or may use parts of the two guidances referenced above. The latter guidance is titled for "Superfund" projects, but is used for other programs as the information requested is applicable to all investigations (see Section 7.2.2 for further information).

The preparation of QAPrPs, QAPjPs, SAPs and FSPs is the responsibility of the regional Project manager, grant recipient, or contractor. The responsibility for review and approval rests primarily with the RQAM, unless delegated as previously noted to program and state offices. Approval must occur prior to initiating data collection.

2.5.1.6. Standard Operating Procedures (SOPs). Data collection procedures can be standardized and published as written protocols for inclusion by reference in QAPrPs, QAPjPs, SAPs, FSPs, contracts and similar documents, and for use as guidance and technical assistance documents. SOPs are prepared using “Guidance for the Preparation of Standard Operating Procedures (G-6)”, EPA/240/B-01/004, March 2001. Program specific SOPs are prepared primarily by four groups: EPA Region 9, when performing the lead in an EDCA; Interagency agreements (IAG) recipients (such as the U.S. Army Corps of Engineers, U.S. Geological Survey, or U.S. Department of Energy), grantees (such as states, tribes, and universities); and responsible parties, or other government entities (i.e., Federal facilities) where EPA has retained oversight and decision making responsibilities. The responsibility for preparing, updating and approving SOPs rests with these parties, although the Region 9 QAO may comment or require changes depending on the nature of the project. Wherever possible, these groups are encouraged to develop program-specific SOPs for recurring activities. The QAO staff may assist in the preparation of site-specific and program-specific sampling and analytical SOPs. To avoid duplication of effort, an SOP prepared by one program may be utilized by another program, when appropriate; however, this will only be done with the permission of the originating party unless that party is under contract to EPA..

2.5.1.7. Data Quality Indicator Tables. To facilitate its own requests for analytical support, the Region 9 QAO has developed data quality indicator (DQI) tables for most of the more commonly requested analytical methods it uses in procuring analytical services. The DQI tables specify detailed calibration and QC requirements for each analytical method including numerical limits and corrective action procedures which must be followed in the criteria are not met. DQI tables are also provided to grantees, such as tribes, upon request, for use in procuring analytical support.

SECTION 3
PERSONNEL QUALIFICATIONS AND TRAINING

The success of an environmental program depends on the capabilities of the individuals who carry it out. These include project and program managers, POs, field and laboratory staff, and QAO staff.

3.1 Region 9 Personnel Qualifications and Training

The Human Resources Office (HRO) of the PMD conducts both employment and training activities for the Region, based on expressed management needs. Management defines the duties, responsibilities and required performance levels for personnel involved in environmental programs and data collection. This is to ensure personnel have the needed academic background, training and experience to fulfill the necessary function. HR experts then translate these requirements into the appropriate position classifications and grade levels.

Technical staff are generally hired under scientific classifications: environmental scientists, life scientists, environmental engineer, chemist, etc. The knowledge and qualifications necessary to receive these designations are dictated by Federal Office of Personnel Management classification standards.

The knowledge and certifications for technical personnel performing certain duties are further specified by Agency directives:

- Compliance inspectors/field investigators (personnel who conduct field activities that may lead to or support enforcement actions) (EPA Order 3500.1);
- Contract managers (EPA Contract Management Manual, Chapters 7 and 8);
- Health and safety (EPA Orders 1440.2 and 1440.3).

3.2 Training

3.2.1. Technical training. Training requirements for technical staff generally are specified by Agency directives (cited in §3.1) as prerequisites for certification. Supervisors may specify training for individuals on a case-by-case basis. Staff members also have individual responsibility for maintaining and expanding their qualifications. Each division/office has been requested to designate a training contact who organizes training to meet the programs' needs. Training courses developed to comply with Regional policies are generally non-technical, in areas such as cultural diversity.

3.2.2. Professional development. To encourage professional development beyond initial qualifications, HRO sponsors training to maintain or increase the work effectiveness of technical employees. The Regional Training Catalog identifies the following training categories:

- •Communications
- •Office of Civil Rights
- •Management Development
- •Financial & Contract Management
- •Personal & Professional Development
- •Legal & Regulatory
- •Health & Safety
- •Human Resources Development
- •Science & Technology
- •Information Systems Technology

Regional management supports the belief that regular training is needed to maintain and improve performance by providing training information, and by paying costs of training taken in-house and also at external institutions. Rotational work assignments, such as the Intergovernmental Personnel Agreement Act (IPA) and career rotation programs, are also encouraged.

3.2.3. Documentation of Training. HRO is the primary office which maintains personnel training records. Training completed is documented on EPA form SF-182, which is maintained in the employee's personnel file. The effectiveness of the training is assessed by HRO's review of the course evaluation portion of the SF-182 and by the supervisor's observation of work performance. Course evaluation forms are used to provide feedback to course instructors.

3.3. Regional QA Training

The QAO staff have developed a Region-wide QA training program. The QAO provides training to Regional staff, representatives of other federal agencies, state grant recipients, and Indian tribes on QA-related topics including:

- orientation to QA management
- preparation of QAPrPs, QAPjPs, SAPs and navigating the review and approval of these documents
- DQOs
- project management
- sample collection, sample packaging and shipping, paperwork for sample collection,
- data generation and acquisition
- assessment and oversight
- data validation and usability
- QA oversight activities

Attendance at QAO training is expected of Regional staff involved in EDCAs.

As stated in Section 2.4.3, the primary means for identifying training needs are through the audit process, surveys, and one-to-one discussions between the QAO and the programs. The QAO attempts to respond to all classroom oriented training requests, where possible and as necessary (e.g., training on how to implement the new QA policies regarding collection of Volatile Organic Compounds (VOC) in soil or educating POs signing small grants on the breadth of EDCAs performed). Numerous one-one-one trainings are provided by the QA staff.

Training, although resource consuming, is a necessary component of the QAO's responsibilities, as many of the Region's project managers and contractors lack the experience, training to personally carry out technical duties, or are reluctant to take ownership of QA functions.

QAO staff involved in providing training are usually those experienced in performing the function for which training is being provided (i.e., QA review, data validation, sample scheduling, and QA oversight).

3.3.1. QAO Staff Training. QAO staff consist of environmental scientists, chemists, engineers, and life scientists. Training for QAO staff is encouraged by the RQAM to keep QAO staff abreast of innovations affecting their areas of responsibility.

QA staff who conduct the majority of the QA review functions or oversees the ESAT contractor’s performance of those activities, become qualified primarily through concurrent work assignments with experienced staff members.

SECTION 4
PROCUREMENT OF ITEMS AND SERVICES

4.1 Procurement Activities

The procurement activities in the Regional Office consist of purchases, usually under $2,500, made on the Government Purchase Card by authorized Purchase Card Holders and all other purchases and contracts made by the Contracts Office in the Policy and Management Division. Simplified Procurements are those procurements for supplies and services under $100,000 and basically are of an "off the shelf" nature. The Regional Contracts Office places and administers selected contracts over $100,000, a current example of which is the Regional Analytical Lab contract. The Regional Contracts Office places and administers orders against Government Wide Agency Contracts and Schedule Contracts of other agencies. Additionally, the Regional Contract Office administers those contracts placed for the Region by the Office of Acquisition Management at Headquarters (HQ). Currently, the Regional Contracts Office administers one RAC, one SESS contract, one ERRS contract, and one START contract issued by HQ. The statements of work for these contracts were developed by the Regional Superfund Program. Contract actions for other Program Offices are developed by the user in the appropriate Division.

4.1.1. Contracts Involving EDCAs. Regional procurements take place in several phases. A Program Office first identifies its requirements and develops the technical specifications, evaluation criteria, and any certifications needed. These are documented on an electronic Purchase Request Form with attachments which is electronically reviewed and approved by the Branch Chief and Division Director, funded by the appropriate funding control person, and submitted to the Contracting Officer (CO) for action. Changes to procurement documents undergo the same electronic review and approval sequence.

Whether the procurement is to be made at the Regional Contracting Office or HQ, procurement of the requested items or services is undertaken by the CO, according to Federal and Agency regulations detailed in the Federal Acquisition Regulations (FAR), EPA Acquisition Handbook, EPA Contracts Management Manual, and the Procurement Policy Notice (PPN) No. 01-02, "Guidance for Use of Higher-level Contract Quality Requirements in Acquisitions," March 2001 (Appendix J) which provides guidelines for addressing EPA's quality requirements for environmental data collection and use. This PPN utilizes a new FAR clause, FAR 52.246-11, for EPA's higher-level contract quality requirements and was developed by the Office of Acquisition Management to update the quality requirements formerly defined in EPAAR 1546.2. The procurement process is documented in the contracts file pertaining to the particular action.

When EDCAs are performed by contractors, QA requirements are integrated into the statement of work. It is communicated to the contractor that a QAPjP, SAP, or FSP is required every time a new sampling and analysis activity is begun. In most cases, a blanket QAPjP is due

with the proposal or else just after contract award. The QAO reviews contract language and often is part of the proposal review team if it will include many tasks involving the collecting of data. As each task is assigned, the appropriate QA planning document is generated under the task and forwarded by the Work Assignment Manager (WAM) or PO to the QAO for review. Once the QAO completes its review and approval of the planning document, the WAM or PO has immediate responsibility for performing oversight to ensure the activities covered in the planning document are implemented. When subcontractors are used, the acquisition regulations require that responsibility be maintained by the prime contractors; therefore, there is no oversight responsibility by Regional WAM or PO of sub-contractors.

4.1.2. Grants and Financial Assistance Agreements Involving EDCAs. Region 9, as do most Regions, provides financial assistance to states, tribes, and non-profit organizations who assist the Agency in carrying out its mission. Many of the recipients of these assistance agreements perform environmental measurements and, therefore, are required under 40 CFR 31.45 to demonstrate that they have a quality system in place. In order to fund these organizations, POs in Region 9 must generate a "Decision Memo" which authorizes the transfer of funds from EPA to the grantee. These memoranda include a section which discusses the environmental measurement aspects of the project and contain a concurrence block for the RQAM to sign.

During these reviews, the RQAM or designee determines whether a grant condition needs to be added specifying a QMP and/or QAPP and/or some other type of a QA planning document must be prepared. If the grant is a continuing one, but no new and/or different measurements are planned, the Decision Memo documents this fact and no condition is placed in the grant. If the grant is new, if there are new measurement activities, if a plan is currently being written or if a plan is under review, a condition is placed in the grant stating that no environmental measurements are to take place before the QA planning documents are approved. The status of projects with respect to their QA documentation is tracked using the Document Review database, further described in Section 5. The database is used extensively during the grant funding cycle to determine whether QA conditions are required.

Once the recipient signs the grant and returns it to EPA, the grant condition becomes final. It has not been Region 9 policy to require the submittal of QA Plans or related documents with proposals or work plans; all documents are created after the grant is funded. This means that grant funds can be used to prepare the QA Plan which, in Region 9's experience, results in a better more complete and thorough product and a more efficient use of grant recipient resources. Generally, the QAO does not monitor grant progress to determine when a QA Plan is due; this is left up to the PO and the grantee. Grant funds can be expended provided that they are not used for the taking of measurements. Thus, preparation of QA Plans and SOPs, purchase of equipment, contracting with environmental laboratories, hiring of consultants, etc. are all permitted since they do not directly involve collecting or using environmental data.

The grantee and EPA PO work together to determine when the preparation of QA Planning documents is required. These documents are submitted to the PO since they are deliverables under the grant or cooperative agreement. The PO is responsible for reviewing the QA planning documents with program goals and objectives. The document is then forwarded to the QAO for its review. Once the QAO completes its review and approval of the planning document, immediate oversight responsibilities reside with the PO or Task Monitor.

4.2. Oversight of Quality

The EPA WAM for the contract and PO for grants and interagency agreements establish the framework for monitoring the quality of items or services by incorporating inspection and acceptance criteria into contract statements of work or work plans for grant/interagency agreement. They are responsible for oversight and for ensuring that products delivered meet contract and grant/interagency agreement requirements.

Oversight of contractor QA products is accomplished mainly by the efforts of the Document Review Team, which is headed by a Team Leader. This Team reviews contractor quality planning documents to ensure that Agency policy and contractual requirements related to quality assurance are being met. The Team members generate comments on contractor documents which are then provided, with RQAM approval to the Project Officer, Remedial Project Manager (RPM), or other Agency individual responsible for the particular contract or work assignment. These individuals then communicate the comments to the contractor and track the contractor's response.

SECTION 5
QUALITY DOCUMENTATION AND RECORDS

5.1 Regional Records Management System

A records management program is a framework to provide records storage and timely retrieval, secure storage and preservation of sensitive records, minimize potential loss or damage to records, and provide cost effective use of available storage space. All staff are responsible for ensuring that Agency records are maintained in a proper manner.

Regional records management policies and guidance are contained in Regional Order 2160 (Records Management Policies and Procedures) (Appendix K) and in the Regional Records Management Manual. The Manual contains information on records management topics such as records and files management, transferring records to the Federal Records Center (FRC), requesting records from the FRC, and records retention and destruction. The disposition of records is governed by the General Records Retention Schedules and EPA Retention Schedules, which specify how long EPA records must be kept and when they can be destroyed.

Records management assistance and training are provided by the Regional Records Management Officer (RMO), who is located in the Computer Systems, LAN and Telecom Program of the Policy and Management Division. The RMO also serves as the primary liaison with the local FRC, coordinates the transfer and retrieval of records, and assists offices in completing necessary forms and handling special situations.

5.2 QA Documentation and Records

All EDCAs conducted by Agency personnel, its contractors, grant and interagency agreement recipients are required to have an appropriate QA planning document (QAPrP, QAPjP, SAP, FSP, or WP, etc.) developed and approved by the QAO or QAO designated EPA authorized personnel for each environmental data collection activity prior to the initiation of data collection.

A Document Review database developed with assistance from the Information Resources Management Program, and maintained by the QAO is used to monitor and track the review status of QA planning documents (QMPs, QAPrPs, QAPjPs, SAPs, FSPs, work plans, and other QA-related documents) reviewed by the QAO. Figure 1 is an example spreadsheet, showing the information recorded and tracked. Each QA planning document received by the QAO is entered into the database. The document is assigned a unique document control number (DCN). This unique DCN enables the QAO to track the document from initial submittal to final approval and record the number of times it was reviewed by the QAO. Once a document is approved, the DCN is not used again; even if a document is amended or revised; a new DCN is assigned. The

database also has the ability to sort on any of its fields. For example, all documents submitted by tribes, all documents from a particular Superfund site, all the backlog of a particular reviewer, all documents received in a specific time frame and so on are all examples of sorts used on a regular basis. The database also contains counting capabilities which enable workload and timeliness statistics to be calculated. The database is used extensively to determine the status of QA documentation for on-going grants and cooperative agreements so that appropriate conditions can be added to grants.

All QA related documentation (i.e., QA grant requirements, approved QAPjPs, FSPs, lab and field audit reports, inspection reports, system reviews, corrective action reports) are maintained by the responsible project officer or remedial project manager, *per Section 1.2.2*, or by the QAO at the program client's request, and are subject to periodic review by the RQAM. These documents will be maintained in accordance with Regional Order 2160. Lists of QAPjPs approved for continuous EDCAs and of approved grant QA documents are maintained by QAO to initiate periodic revisions of approved QAPjPs, to follow-through on commitments for new QAPjP submittals, or to prompt the performance of technical reviews.

5.2.1 Control of QA Guidance Documents

QA guidance documents are developed for Regional use by the QAO in the absence of Agency-wide guidance, or when detailed Regional processes need to be documented. Examples include Regional guidances for preparing non-CLP laboratory data packages (Appendix F); QAPrPs (Appendix H); and QAPjPs for Superfund remedial activities, and FSPs for EPA-lead and private-party-lead sampling events (Appendix J). These guidances are assigned unique numbers (e.g., R9QA/001.1 for Sampling and Analysis Plan (SAP) Guidance and Template, Version 1, EPA Analytical Services Used (April, 2000) (draft)). The document tracking number is increased by one to R9QA/001.2 for the example provided when the guidance is revised.

Regional QA guidances are drafted by QAO staff experienced in the subject area covered, and reviewed by the RQAM and other subject-area peers before approval by the RQAM for distribution. Document control format is used, and unique document control numbers are assigned to each document. Revisions are prepared and transmitted as needs are identified by QAO staff.

Regional guidances are available from the QAO or QA Web page located at: http://www.epa.gov/region09/qa/r9-qadocs.html.

SECTION 6
COMPUTER HARDWARE & SOFTWARE

6.1 Regional Information Resources Management Policies

The Information Resources Management (IRM) program of the PMD has the primary responsibility for setting policy and guidance for the management and development of computer-related program support. The Regional IRM Program is managed by the Senior Information Management Officer (SIRMO) which directs the Office of Computer Operations, responsible for the Local Area Network, Geographic Information Systems, information security, and application development; and the Office of Personal Computing and Information Access, responsible for desktop support, training, and records management. Personal Computing/Local Area Network coordinators in each Division act as liaisons between IRM and their divisional co-workers. Database administrators for each program office coordinate activities relating to their associated databases. Since these are national databases, requirements are defined by the national program offices at HQ.

Regional data are collected, processed, and managed by the program offices. IRM manages the hardware, software and networking platforms. IRM also coordinates with the program offices on hardware and software issues, purchases and upgrades, and pilot programs.

EPA's Information Technology Architecture Road Map is an organized collection of products and technologies that define the standards and guidelines supporting the technical design of Agency information systems. Furthermore, the Agency's IRM program is subject to the Information Technology Reform Act of 1966 (Division E of Public Law 104-106). Region 9 IRM follows Agency-wide guidances: "System Design and Development Guidance," "Supplemental Guidance to EPA's System Design and Development Guidance," "Operations and Maintenance Manual," and "IRM Policy Manual."

OMB Circular A-130 No. 4 requires all federal agencies have an information security program. The issue of information security pervades all aspects of the Agency's information technology infrastructure. An information security program that is consistently administered across the entire Agency is critical to the Agency's ability to sustain and maintain its ongoing operations. The Agency must achieve an appropriate balance between providing safe access to accurate environmental information and protecting the information assets of the Agency.

6.1.1. Use of Computer Hardware and Software. The purchase of computer hardware and software by Region 9 and its contractors is governed by Regional Order R2100 (Information Resources Management Hardware Policy) and Regional Order R2100.1 (Information Resources Management Software Policy), which are provided in Appendix L. The Regional policies are designed to ensure that the computer hardware and software used meet program requirements,

and are consistent with the Agency-wide standards they cite.

6.1.1.1. Assessment of Impacts of Hardware and Software Changes. Most requests for computer system development, maintenance, enhancements, etc. are initiated by clients in the program Divisions. IRM works closely with clients to determine their needs, options and implementation schedule.

Success or failure of system developments is measured by the level of client satisfaction. IRM has various mechanisms in place to monitor customer satisfaction, including surveys, outreach meetings to discuss IRM-related issues, solicitation of client feedback and resolution of differences, and an open-door policy.

The assessment of the potential impacts of IRM changes is emphasized before implementation. Broad-based projects impacting the entire Region generally require support by the SIRMO. Major changes are discussed with the Region's Labor Management Partnership Council.

6.1.1.2. Development of Software. The software applications which are developed in Region 9 are small in scope. They are primarily user-oriented, and not utilized outside the Region. Database applications are developed using existing software only. A typical example is a Lotus Notes document tracking system developed by IRM for program offices. Regional personnel are discouraged from developing their own software.

The development process includes the following steps:

- meetings with the user to determine user needs;
- development, validation, and verification of the application;
- preparation and delivery of user documentation;
- preparation by the developer of a manual on the development process.

IRM programming staff follow "Programming Guidelines" (1991). This Regional document parallels and simplifies EPA and Federal policies and procedures.

6.2. Standards for Computer-Generated Data

Regional IRM data standards are consistent with Agency-wide standards: Corel Wordperfect (word-processing), Oracle (database management), Lotus 1-2-3 (spreadsheet), Lotus Notes (communications), and ARCInfo (GIS). Regional contracts require conformance with the Regional and Agency standards for hardware, software, and data delivery format. Seven-point justifications for computer related purchases require IRM concurrence. The monitoring of compliance is the responsibility of Project Officers.

6.3 Regional Environmental Data Storage and Retrieval

Monitoring data are in some instances stored on computer databases. Some are databases developed by HQ program offices (e.g., Store It and Retrieval [STORET]) while others are developed for specific users (e.g., Superfund contractor data from remedial investigations). The database software includes QA routines. These routines are assumed by the user to be adequate for the intended use of the database. The responsibility for quality control of data entry and corrections belongs to the program Divisions which maintain the databases.

SECTION 7
QUALITY PLANNING

7.1 Regional Planning Process

7.1.1. Annual Program Planning. The primary vehicles for annual planning in the Region are the budget process, the Strategic Targeted Activities for Results System (STARS), GPRA and the State/EPA Agreement process. The Deputy Regional Administrator allocates resources to each Division for the management and operation of specific programs, based on the Region's anticipated budget. Program managers must then balance their available resources with their need for support, e.g., QA support from QAO, to meet GPRA, program goals, and STARS commitments. Negotiations between customers and suppliers within the Regional Office result finally in work commitments.

Most Regional work activities are mandated by policy guidance, tracked commitments to HQ, and Program Office WPs. A WP is prepared by each Program Office prior to the start of a fiscal year. It contains estimates of the work activities for that year. Ideally, the WP is developed in consultation with the Program Offices' customers and suppliers. The QAO seeks input from the Divisions it serves in preparing the WP for FY 2001 (Appendix M).

7.1.2. QA Annual Planning. See Section 2.4.8 which discusses QA Annual Planning.

7.2 Planning and Documentation of QA and Related Technical Activities

7.2.1. Data Quality Objectives. Region 9 has integrated the development of DQOs for projects involving EDCAs into the normal process of project planning and design. EDCAs generally begin with project scoping, where project specific DQOs are determined in accordance with "Guidance for the Data Quality Objectives Process," G-4, EPA/600/R-96/055, August 2000, "Data Quality Objectives Process," September 1994 or "Data Quality Objectives Process for Superfund, Interim Final Guidance," September 1993, EPA 540/G93/071 depending on the program involved. The sampling objectives, design strategy for optimizing the information obtained, and the acceptable levels of error (i.e., determining the number of samples to be collected to meet field and lab stated QA/QC criteria with available resources) are determined by the stakeholders, project managers, regional QA staff, risk assessors and other data users, in the project during this process. Outputs of the DQO process are documented in QAPjPs following "EPA Requirements for QA Project Plans," (QA/R-5), EPA/240/B-01/003, March 2001.

DQO's are qualitative and quantitative statements which specify the acceptable error rates associated with environmental measurements for decision making purposes. Sampling designs and quality control criteria for field and laboratory methods and procedures, derived from site-

specific DQOs, should be included in planning documents such as QAPjPs, SAPs or FSPs. Continued communication among project managers, sampling, analytical, and QA staff is necessary to ensure common expectations and understanding of logistics and schedules.

In many cases, especially with state delegated programs, regulatory standards are the main quantitative objective used in decision making. A full DQO process would not be followed in those situations. Instead the focus would be on the quality of the data that are being used for decision making versus those regulatory standards.

7.2.2. QA Planning Documents (QAPrPs, QAPjPs, SAPs and FSPs). An approved QA planning document is required before implementation of an EDCA. These documents are prepared by technical staff responsible for performing the EDCA, and submitted to the QAO for review through the project manager or PO. Project specific QAPjPs, SAPs, and FSPs are prepared using the EPA QA/G-4 guidance which take the EDCA planner through the DQO process for determining project objectives and acceptable levels of confidence for the data to be collected, unless the project involves the application of a regulatory standard, such as water quality standards. If that is the case, these standards would be used instead..

QAPrPs are formatted and prepared following, “EPA Region 9 Guidance for the Preparation of Quality Assurance Program Plans,” (R9/3.1, June, 2001) which incorporate requirements from “EPA Requirements for QA Project Plans” (QA/R-5), EPA/240/B-01/003, March 2001.

FSPs are formatted and prepared following, “Sampling and Analysis Plan (SAP) Guidance and Template, Version 1, EPA Analytical Services Used (R9QA/001.1, April, 2000) or “Sampling and Analysis Plan (SAP) Guidance and Template, Version 2, Private Analytical Services Used (R9QA/002.1, April, 2000) or "Preparation of a U.S. EPA Region 9 Field Sample Plan for EPA-Lead Superfund Projects" (9QA-05-93, August 1993) and "Preparation of a U.S. EPA Region 9 Field Sample Plan for Private and State Lead Superfund Projects", (9QA-06-93, August 1993). The latter guidance is titled for "Superfund" projects, however, it may be used for other programs as the information requested is applicable to all investigations.

Planning documents submitted by the programs such as QAPrPs, QAPjPs, SAPs, or FSPs containing information related to project schedule, milestones, QA/QC requirements and procedures are largely reviewed and approved by QAO prior to collection of environmental measurements. Personnel in media divisions authorized by QAO may also perform reviews. Reviews performed evaluate whether data generated under the plan meet the DQO requirements of the project (i.e., produce data of known quality that can be used for the intended purpose). This review and approval process applies to EPA funded projects, including grants, IAGs, and other EDCAs in which EPA plays an oversight/decision maker role. A multi-disciplinary approach is used by QAO to perform the reviews. Internal peer reviews are performed by QAO staff to ensure QA recommendations on various fields (statistics, marine biology, engineering

design/construction, field and lab methodologies, etc.) are sound and add value to the project.

A percentage of QA planning documents are reviewed by ESAT contractors to supplement QAO's effort. The Region exercises appropriate contract management controls which are approved by the contracting officer. All comments generated by contractor personnel are reviewed by QAO personnel to ensure that no inherently governmental decisions are made by ESAT. These comments are edited and modified by EPA reviewers as necessary prior to being released to clients. ESAT does not make any decisions on approval of QAPrPs, QAPjPs, SAPs, FSPs, or WPs.

Any planning documents which include the use of existing data or data from secondary sources, must specify the criteria used in determining the suitability of the data for their current use. The data are analyzed, evaluated and assessed against their intended use and quality performance criteria of the current plan by representatives of the QAO or other QAO designated EPA authorized personnel.

After approval, the final documents are retained by the project manager. Approved QAPjPs remain in effect for 5 years, at which time they should be revised to reflect the current activities being performed.

After a state, or a state program has an approved QMP and QAPrP(s) in place and the QAO has evaluated the program to ensure that it is meeting EPA standards, the review and approval of some state QAPjPs, SAPs, and FSPs reviews may be delegated to the state. Along the same line, the states are also required, particularly for non-Superfund related EDCAs, to perform data review under the guidelines of the Region's Division offices. This is partially a function of how the project is funded. Usually if the project is funded directly, the QAO will perform the review. If the project is part of block grant activities for a delegated program, the state will perform the review. This system is not fully in place for Region 9 states at this time due to many QMPs and QAPrPs still being in the review stage, but this should change in the future as more of these plans are approved, and as states expand their QA programs.

7.2.3. Data Evaluation. Data acquired by the Region are reviewed as noted in Section 2.4.6. Once the data are reviewed, the Project Manager is responsible for performing the final determination as to whether the data can be used for the purpose collected. Assistance is provided to the Project Manager, by the QAO upon request.

7.2.4. Health and Safety Plans. Regional FSP guidance requires the preparation and submission of a site health and safety (H&S) plan whenever the protection level is above "D" (i.e., A, B, C). Information on H&S plan preparation can be obtained through the Regional Health and Safety Officer, currently Jeff Woodlee (415) 744-1487. The plan is reviewed and approved by the Regional Industrial Hygienist for EDCAs performed by Regional staff. Review and approval of health and safety plans prepared for EDCAs performed by contractors or other

non-EPA units are the parent organizations' responsibility.

SECTION 8
QUALITY IMPLEMENTATION, ASSESSMENT AND RESPONSE

8.1 Implementation

8.1.1. Project Management. Project officers and managers are responsible for ensuring the EDCAs are conducted in conformance with their Program authorities and regulations and in accordance with approved QA planning documents (QMP, QAPrP, QAPjP, SAP, or FSP) and standard operating procedures. Responsibilities previously identified in Section 1.2.2 are also expected to be carried out by the project officers and managers. The project officers and managers pursue conformance of the EDCA described in the planning documents by assigning leadership roles and responsibilities for the QA activities discussed in the QA planning documents. One or several of the following oversight tools may be used by project officers or managers in the execution of EDCAs: data reviews, audits (lab, field, technical), observation of contractor performing work, and use of performance evaluation samples (PES). Project officers/managers may either perform these oversight functions themselves or may request QAO or Regional Laboratory staff assistance to perform these functions. When ever these oversight tools are used, it is expected a report identifying strengths and areas for improvement be generated. Where these tools identify QA/QC deficiencies, effective corrective action is expected to be completed and documented by the responsible project officer or manager.

Independent performance monitoring of selected projects by the QAO also encourages conformance (i.e., use of performance evaluation samples on randomly selected sites; periodic audits of field or laboratory activities where planning documents indicate QA/QC activities may not be carried out as stated (i.e., numerous revisions or lack of clarity indicate lack of understanding or experience in the conduct of activity).

8.1.2 Standard Operating Procedures. Specific field and laboratory data collection procedures and technical operations such as data validation can be documented as standard operating procedures (SOPs) for inclusion by reference in QA planning documents, contracts or agreements. SOPs are a means of establishing uniformity throughout an EDCA and of integrating quality control provisions into routine operations.

The party that implements the procedure or that generates the QMP, QAPrP, or QAPjP is responsible for the preparation of SOPs. Use of existing SOPs is also encouraged. SOPs provide specific step-by-step procedures for carrying out generic methods for sample collection, field or laboratory analysis, data review, data assessment, etc. Effective and reliable SOPs help eliminate uncertainties in data quality. SOPs define the acceptable practice in which a sequence of procedures is to be performed. They can help to provide uniformity and minimize inconsistencies in the performance or misapplication of laboratory and field methods. SOPs for the environmental data collection activities are referenced in site-specific QA planning documents. When the scope of work changes which may require the use of different or

additional lab and field methods or if new regulations necessitate the use of new methodologies, existing SOPs should be reviewed and modified accordingly.

SOPs can be written simply so that a potential user with basic experience and training can readily understand and apply the procedures to meet its full intent. SOPs prepared in Region 9 follow regulatory requirements or "Guidance for the Preparation of Standard Operating Procedures (G-6)," EPA/240/B-01/004, March 2001 and are consistent with sound scientific and engineering principles. Procedures developed as SOPs, are reviewed and approved by the RQAM through the approval process. In routine monitoring programs such as those under state and IAGs, SOPs are reviewed concurrently with the review and update of the parent QA planning document.

SOPs developed for EDCAs at Region 9 should at a minimum, include the following:

1. Title Page;
2. Control Documentation;
    a) Short Title/ID#
    b) Revision #
    c) Date
    d) Page 1 of __
3. Table of Contents.

The contents should include:

a) Purpose of Standard Operating Procedures;
b) Applicability;
c) Procedural information;
d) QA/QC practices to be applied;
e) Checklists used (if applicable);
f) References used.

8.1.2.1. Review and Approval of EDCA Related SOPs. When EPA is the lead agency for the EDCA, field SOPs are usually prepared by EPA contractors or EPA personnel. If EPA contracts with non-CLP laboratories or when data review or validation is conducted by an EPA contractor, then laboratory SOPs or QA manuals and validation SOPs, respectively, are requested by the project manager and submitted for review by the QAO. SOPs should be submitted to QAO as part of or as an addendum to the QMP, QAPrP, or QAPjP for review.

Where the states and other grantees perform EDCAs or IAGs, field SOPs are usually prepared by states and grantees or their contractors. Laboratory SOPs should be prepared by personnel who operate the laboratory. If the states or grantees use contract laboratories, then laboratory SOPs and QA manuals should be requested of them. States or grantees can independently approve the use of their contractors' SOPs under EPA grants only when this

function is stated in its approved QMP or QAPrP; otherwise SOPs should be submitted to the QAO as part of or as an addendum to the QMP, QAPrP, or QAPjP.

Where EPA has oversight responsibilities and is the final decision maker for EDCAs performed by governmental or responsible parties, the SOPs are prepared by the government agency, responsible party or their contractors performing the EDCA. These SOPs and manuals are reviewed by the project managers within the individual agency or organization conducting the EDCA to ensure that the SOPs reflect the actual activities performed. These field and laboratory SOPs and QA manuals should be requested by EPA project managers and submitted to the QAO as part of or as an addendum to the QA planning document for review.

All review comments should be satisfactorily addressed by the authors of the SOPs. Final approval should be given by the QAO or its authorized representative before any SOP is put into actual use.

8.1.2.2. Frequency of SOP Review and Update. EDCA related SOPs are reviewed every year by the party responsible for performing the EDCA to ensure that the SOPs are still adequate and meet current standards. SOP revisions are prompted when the following occur and should be reviewed yearly:

a) significant update/revision of procedures to improve method efficiency or changes due to instrument up-grades or new technologies.

b) modification of methods or previously approved SOPs to address project or site-specific needs (e.g., need a lower detection limit for an analytical method).

c) promulgation of new regulations or their revisions requiring the addition of new or revisions of existing SOPs due to more stringent and higher environmental standards.

SOPs affected by these criteria will need to be updated during the year of the change. The one year rule for revision and update may be waived on a case-by-case basis due to resource constraints involved or where the change is so minor that the quality of the data generated are unaffected. In these cases the minimum frequency for update will be every three years. When changes occur, EDCA related SOPs are revised and submitted to QAO for review and approval as addendums to the QA planning documents. Periodic verification should be performed by the organization responsible for performing the EDCA to ensure that activities are conducted in accordance with SOPs. SOPs that have been updated will be archived per guidance provided in Regional Order 2160 and the Regional Records Management Manual.

SECTION 9
QUALITY ASSESSMENT AND RESPONSE

All EDCAS require a mechanism for monitoring the effectiveness and adequacy of the QA measures integrated into the program. The standard oversight mechanism is the audit. The bases of the audit are the approved planning documents identified in Section 2.4.7. An audit compares the data quality needs of the program and the documented procedures for obtaining the data against what is actually implemented and the resulting quality of the data obtained. An audit can pinpoint the weak link in the data collection activity, whether it be at the managerial, sample plan preparation, sample collection, analytical, data review, or data usage stages.

Overall, the audit is expected to: identify strengths and weaknesses; cause corrective actions to be taken to alleviate problems, facilitate the initiation of changes to enhance the QA program; serve as a vehicle for providing technical assistance; enhance awareness and understanding of QA/QC policies and procedures; and provide a measurement of the effectiveness of QC in assuring the quality of data.

Audits or reviews are scheduled and performed by the QAO on Regional programs as needed and as resources allow. They are intended to provide an overview of the effectiveness of the QA measures adopted by each program. QAO staff responsible for conducting these audits are trained to perform these reviews, and experienced in effectively applying quality assurance in EDCAs. Four types of audits or reviews are conducted, as explained below.

9.1 Management System Reviews (MSR)

In order to assess whether the goals of the Agency's mandated Quality System have been met, the QAO conducts periodic MSRs to evaluate the effectiveness of the QA program implemented in the Region and States. They are further used to evaluate whether the documented Quality System is in conformance with what is actually implemented. The management and technical activities associated with implementing Quality Assurance (QA) and Quality Control (QC) for ensuring the collection of data of known quality are reviewed, along with the roles, responsibilities, and authorities of the individuals implementing the Quality System (i.e., what is the QA mission statement for the organization?; is the Quality System supported by Senior managers?; are planning documents produced?; is the DQO planning process or similar used?; is QA training available?; are internal reviews performed to determine conformance of planning documents with actual performance and implementation?; is follow-up performed to determine the effectiveness and consistency of corrective actions?).

MSRs are meant to ensure that an organization has an effective QA System in place and that it is provided the necessary resources and qualified individuals to enable it to generate data of known quality. The MSRs obtain an accurate description of staff understanding of QA roles and responsibilities and staff skills and knowledge of QA practices and principles required for

effective execution of QA activities. The MSRs also evaluate adherence to the Region's QA documentation requirements. MSRs further reveal the proficiency of the Region's QA system in auditing, identifying errors and rectifying QA/QC deficiencies.

MSRs will be conducted for both EPA and non-EPA funded EDCAs in which EPA has an oversight responsibility or uses the environmental data for decision making purposes. EPA funded EDCAs include work done under cooperative agreements such as grants and IAGs. For non-EPA funded activities conducted by external programs such as Federal facilities, these organizations maintain primary responsibility for assessing their Quality System. It is required that the Federal facilities MSR report be submitted to the EPA for review and comment. MSRs of non-EPA funded activities assesses EPA's QA oversight responsibilities.

The Regional MSRs will be conducted in accordance with the "Guidance for Preparing, Conducting, and Reporting the Results of Management Systems Reviews (EPA QA/G-3)," January 1994. At a minimum, one MSR will be performed on a Regional program, Regional Laboratory and on an EPA funded state program each year. However, an MSR will be triggered by severe and persistent QC failures or non-compliance identified through routine and standard field/lab audits and other quality checks.

MSRs, in most cases, will be conducted by the QAO. The audit process begins with the RQAM contacting the management of the office and/or state to be audited. The RQAM then informs them of the audit to be performed and the purpose of the MSR. Participation by non-QA regional staff members will be encouraged and agreed upon by the QAO and the office with which the MSR will be conducted. When performing an MSR on programs in the Region, non-QA staff will be selected from programs other than that which is being audited. When the states are audited, non-QA staff members directly related to the state program being evaluated will be allowed to participate in the MSRs.

Following the agreement between the QAO and the office to be reviewed, the audit is scheduled and performed by the QAO. The MSR team, comprised of QA and, in some cases, non-QA staff, will prepare a draft summary report to be submitted to the director of the Division in which the audited program is located, and to the ARA. The report resulting from an MSR will describe when, how, and by whom the audit was conducted, what specific items were reviewed, a summary of audit findings (overall program assessment and significant findings), and recommendations for corrective actions as necessary. The program managers and/or state agency prepares a response to the recommendations contained in the MSR report within the time frame agreed upon between the RQAM and the program or state. The report is finalized upon receipt of a response from the organization reviewed. The organization reviewed is then responsible for ensuring that prompt corrective action takes place on any findings made.

9.2 Technical Systems Audits (TSA)

The technical systems audit (TSA) differs from a MSR in that it evaluates the actual data collection aspects of the EDCA. MSRs primarily address the management controls to ensure that data collection activities produce the data quality needed by an organization. TSA review includes, but is not necassarily limited to: field and analytical procedures; planning documents (QMPs, QAPrPs, QAPjPs, SAPs, FSP, etc.); calibration records; QA/QC criteria compliance and records; sampling and measurement procedures; SOPs; personnel qualifications; general facility or laboratory cleanliness or housekeeping; equipment and facilities maintenance and repair records, and control charts.

Field audits are conducted to verify that sample collection, shipping, and associated procedures are consistent with those specified in the QMP, QAPjP or FSP. The EDCAs for which field audits are regularly performed are identified in Tables 1A-6A. Appendix M contains the Regional field audit strategy and checklists used. The actual frequency of audits scheduled depends on the resources available for the Field and Biology Team/QAO audit staff.

On-site audits of Contract Laboratory Program (CLP) laboratories located in the Region are performed by the Regional CLP-PO who is located in QAO, at least once a year. Standard CLP audit checklists are used, in conjunction with on-going reviews of data validation reports and other contract compliance information. The evaluation reports from these audits are used to identify and remedy laboratory performance problems. Repeat audits are made on an as-needed basis to resolve laboratory problems. When problems are identified, the CLP-PO oversees the implementation of laboratory corrective action, or contract action if necessary. Note that if no laboratories within Region 9 are currently under contract to EPA, the CLP-PO may be requested to audit laboratories in other Regions. This effort, however, is outside the scope of this QMP, as it is conducted in response to requests from Superfund staff at Headquarters.

Audits are conducted on non-CLP laboratories including those used by Superfund PRPs and Federal Facilities, RCRA owner-operated laboratories, and others, according to an audit strategy (described in Appendix N), or as requested. The CLP audit checklists are used as the basis for performing these audits.

Laboratory certification audits of State, Territory, and Tribal drinking water laboratories are conducted by Regional laboratory certification officers in LP, once every three years. In addition, annual overviews of certification audits of private laboratories by State certification staff are conducted. Procedures and checklists for these audits are defined in the laboratory certification manuals published by the National Exposure Research Laboratory (NERL) - Cincinnati.

For both field and laboratory audits, prepared reports describe when, how and by whom the audit was conducted, what specific procedures were reviewed, a summary of the findings,

and recommendations for corrective action. The audit report is transmitted to the audited office, the program manager, and the PO, as appropriate. The audited organization is responsible for ensuring that prompt corrective action takes place. Follow-up activities vary with the project.

9.3 Data Validation

Data validation is a process of evaluating data and QC documentation, and assessing the quality of data generated. It is used as one of the many tools for performing QA/QC oversight of EDCAs. The QAO performs validation for all programs upon request. The Divisions specify the level of review necessary as identified in Section 2.4.6, to meet project needs. Section 2.4.6 also discusses how data validation can be used for performing QA/QC oversight.

9.4 Performance Evaluation

Performance evaluation assesses the ability of an analytical system to obtain reliable data. It consists of providing reference or performance evaluation samples (PES) to the laboratory for analysis. The PES are prepared using media that most closely resembles the samples being collected from a site (e.g., soil, water). They are then spiked with known concentrations of chemical constituents or pollutants of concern and sent to a laboratory for analysis. The analytical results obtained by the laboratory audited are compared to the known concentrations of the specific parameters contained in the PES to determine if the laboratory properly identified and quantified the constituents within established or calculated control limits. The QAO encourages project managers and their contractors to include PES in their QAPjPs, SAPs, and FSPs. Regional guidance on the use of PES is available from the QAO.

PES of specific parameters are obtained from appropriate laboratories by QAO when needed by the program managers to monitor laboratory performance. Regular infusion of blind PES into the sample stream has been an effective method of quality control for field and laboratory procedures. The use of PES for a project complements the Tiered Data Review process previously described. For example, routine use of PES in on-going monitoring activities not only provides insightful understanding of project data quality, it also helps to reduce the amount of data review otherwise needed. The QAO sends PESs to CLP Laboratories, the Region 9 Laboratory, and QA Office-contracted laboratories such as EMAX. In special situations, the QAO prepares PE samples from neat materials supplied via the Superfund Quality Assurance Technical Support Laboratory in Las Vegas. These samples are taken to the field and submitted blind or double-blind with field samples, to the laboratory. Results and/or data packages submitted to the QAO by the subject laboratory are evaluated for consistency with pre-established acceptance windows. A written report describing the assessment and implications is submitted to the client. Division PO/project managers are responsible for ensuring appropriate, prompt corrective action takes place; assistance is provided by the QAO upon request.

The LP coordinates the regularly-scheduled Water Supply and Water Pollution PE Studies, in which participation is mandatory for designated laboratories, for the Agency-wide Public Water Supply and NPDES programs. Procedures for these evaluations are dictated by NERL-Cincinnati and the National Institute of Standards and Technology. Laboratories which exceed the statistical acceptance limits are requested to evaluate the source of differences and report their corrective actions to the Region.

SECTION 10
QUALITY IMPROVEMENT

The QAO is very active in ensuring that conditions adverse to quality are prevented, identified and promptly corrected and that actions taken toward correction are tracked to completion. Continual quality improvement of the Quality System in Region 9 begins with conducting EDCAs in accordance with approved planning documents (QAPjPs, SAPs, and FSPs. Planning documents are approved by the RQAM);, and relies on the following measures:

1) Provision of effective QA training on planning document preparation, sampling, analysis and data assessment.

2) Conduct of effective MSRs, Field and Lab audits by QAO;

3) MSRs Conducted by QS;

4) Performance of corrective action on deficiencies identified through MSRs and other EDCA related audits;

5) Effective communication between all levels of staff, management, partners (i.e., States, Tribes, Territorial representatives) with the QAO;

6) Support by Senior Management of the Region's Quality System.

10.1 Training

Training provided by the QA Office serve two purposes: 1) educational tool to provide information on the QA measures available that can be performed to ensure the collection of data of known quality such as generation of planning documents, identification of data quality indicators, etc., and 2) to circumvent data quality concerns before they arise. QA 101 previously noted in Section 1.2.2 will introduce attendees to the QA activities available to them, including those in this QMP, to identify and potentially prevent quality assurance deficiencies from occurring. Another example, the QAO has sponsored or organized trainings to enable effective collection of soil volatile samples. Without this kind of training, it is uncertain whether individuals responsible for soil volatile sample collection would have the necessary skills to obtain representative soil volatile samples. The training described is a preventive as well as educational tool to enable effective soil volatile samples.

10.2 EDCAs Will be Performed with Approved Planning Documents

Section 2.5 identified documentation as an effective tool for implementing the quality system. This section further states that "All EDCA's will be conducted with an approved planning document". EDCAs conducted in accordance with an approved planning document minimize the potential for data quality deficiencies to arise. This is one purpose of the planning document. It further provides guidance on how activities will be consistently conducted, and provides for the record how EDCA activities were conducted.

10.3 Conduct of effective MSRs, TSAs, Field and Lab audits by QAO

As discussed in Section 9.0, MSRs and TSAs will be conducted. Field and Lab audits will also be utilized as a preventive measure to ensure data collection and generation conforms with approved QA documentation and are capable of generating data of known quality. It is expected that when deficiencies are identified, effective corrective action is expected to be completed and documented by the responsible project officer or manager.

10.4 MSRs Conducted by QS

The QAO relies on the Quality Staff MSRs conducted on the Region's Quality System to contribute towards its continual quality improvement. The QS review is based on the Quality System described in this QMP. The QS review assesses the effectiveness of the Quality System implemented in the Region and verifies conformance of the implemented system with what is documented in the QMP. QS comments identifying areas of QA vulnerability in the Region are addressed by the QAO. The QAO also works with the Division in responding to the comments, in cases where joint responses are needed (i.e., where joint cooperation between the Division and QAO are needed to remedy identified areas of weakness).

10.5 Performance of Corrective Action on Deficiencies Identified through MSRs and other EDCA Related Audits

If the QAO identifies vulnerabilities through the audit process, these vulnerabilities will need to be addressed by the respective office or organization. The QAO will follow up with the respective office or organization to ensure the vulnerability is addressed. Where concerns are remain unaddressed, the RQAM may elevate the vulnerability to a Senior manager as discussed in Section 1.2.2.

10.6 Effective Communication and MSRs

Direct communication with organizations responsible for performing EDCAs is a two way process and a necessary tool for the QAO in detecting and preventing quality problems. These quality problems may be related to the services provided by the QAO, or more systemic problems which affect an organizations ability to produce data of known quality.

The authority of the RQAM is relied upon by Divisions and Regional partners to point out the necessary corrective actions needed to address any QA vulnerability that may arise in EDCAs conducted in Region 9 (Appendix B), extramural agreements, regulatory processes, or day-to-day operations (e.g., use of non-approved methods for Clean Water Act compliance monitoring by a State program). Once a QA weakness has been identified, either by the Division or QAO, the QAO meets with the Division office to work on a mutually acceptable resolution. The resolution is retained by the QAO in a policy, memorandum of agreement or planning document. Follow-up is performed by the QAO with the Division to ensure the resolution reached has been implemented.

Similarly, when a Division or a partner to the Region communicates that QA vulnerability exists within its program or a program it oversees, the QAO may elect to perform an audit. The audits are conducted as discussed in Section 9.2.1 and 9.2.2. The QA planning documents discussed in Section 2.5.1 form the basis for performing the reviews. Upon completion of the review, Divisions or responsible organizations are expected to address any audit findings in writing, documenting the corrective measures to be implemented. Follow-up is performed by the QAO with the Division to ensure the resolution reached has been implemented.

10.7 Senior Management Support of the Quality System Implemented at Region 9

As noted in Section 1.2.2, Senior management support is necessary for ensuring an effective, and successful Quality System. Senior managers provide support and leadership of the Quality System in Region 9 through the empowerment of staff, encouraging-reward planned risk taking and innovation, and fostering open lines of communication.

If a dispute should arise that the RQAM is unable to successfully bring to closure, the issue is brought to the ARA's attention for resolution with the responsible Division. Resolutions reached are consistent with this QMP and Agency mandates related to QA.

SECTION 11
LABORATORY PROGRAM

11.1 Mission and Operations

11.1.1. Mission. The Laboratory Program is located in a full-service state of the art facility specializing in chemical and biological analysis and field sampling services. The mission of the Laboratory Program is to provide quality analytical data in support of EPA regional and national programs including hazardous waste, water, air, pesticides and toxics.

In addition to routine analytical analyses, the LP develops expertise and analytical techniques to support specialized regional needs. The Laboratory also provides technical support and training to internal and external laboratories and programs.

The LP provides analysis of air, water, soil, solid and liquid wastes, dust and biota samples (avian, fish and occasionally mammalian tissue). Analytical chemistry capabilities include general inorganic chemistry, metals, volatile organic compounds, semi-volatile organic compounds and pesticides. Biological analysis include toxicity testing and microbiological testing. The Laboratory also offers a variety of field services including field sampling, field audits and on-site field analysis with a Field Analytical Support Project (FASP) mobile laboratory.

11.1.2. Facilities. The LP maintains a 40,000 square foot facility located on the grounds of the University of California Field Station located in Richmond, California. The Laboratory is staffed by approximately 50 EPA and ESAT scientists.

11.1.3. Procurement and Delivery of Laboratory Services. Before samples are analyzed in the LP, a QA planning document is prepared by the requester, and reviewed, and approved by QAO. Exceptions to this must be approved by the Lab Director. This policy is designed to produce analytical requests that are technically sound and meet the data quality needs of the program. The written plan is also a basis for the communication of the requester's analytical needs to the Laboratory. Sample shipping information is provided to the Laboratory by the Regional Sample Control Coordinator for sample tracking purposes.

11.2 QA PROGRAM

The LP is committed to monitoring and optimizing its performance through a variety of QA activities. These activities are implemented under the leadership of the Laboratory's QA Officer. The Laboratory's QA Program is documented in its QA Plan.

The LP routinely analyzes QA/QC samples along with field samples as a basis for determining laboratory performance. The specific QA/QC requirements vary with the program, and are specified in the FSP. The Laboratory also analyzes PES from the Superfund, Drinking Water, and NPDES programs. Occasional double-blind or single-blind samples are also provided as part of laboratory oversight (the LP also is used as a reference laboratory.)

When samples are analyzed by the LP, it sends an analytical report directly to the data user. As explained in the first section of the QAO memorandum to Jane Diamond of the Superfund Division, dated January 23, 2001, Data Quality Review Services for Superfund Projects, (Appendix P), this report is considered to include a Tier 1A data review. The QAO will not perform a separate review unless it is stated in the QA planning document, or requested by the project manager. In fulfilling its role of general oversight of laboratory data quality, the QAO annually performs quality system and targeted audits of the LP. These audits may trigger performance of data review/validation and/or electronic data review by the QAO. Data packages may be requested of the Laboratory by the QAO. When corrective action is indicated, the Laboratory Director and the Laboratory QA Officer are responsible for implementing the necessary changes.

SOPs for routine activities are prepared, reviewed, and updated as needed. A list of the EDCA related SOPs developed by LP is provided in Appendix Q, along with an example. The responsibility for review and approval of LP SOPs rests with the Chemistry Team Leader, the Laboratory QA Officer, and the Laboratory Director.

SECTION 12
ACRONYM LIST

ARA. Assistant Regional Administrator.

CADRE. Computer Aided Data Review and Evaluation.
CLP. Contract Laboratory Program.
CLP-PO. Contract Laboratory Program Project Officer.
CO. Contracting Officer.
CWA. Clean Water Act.

DCN. Document Control Number.
DMRQA. Discharge Monitoring and Quality Assurance.
DQI. Data Quality Indicators.
DQOs. Data Quality Objectives.

EDCA. Environmental Data Collection Activity.
ERRS. Emergency Rapid Remedial Services.
ESAT. Environmental Services Assistance Team.

FAR. Federal Acquisition Regulations.
FASP. Field Analytical Support Program.
FFCB. Federal Facilities Cleanup Branch.
FRC. Federal Records Center.
FSP. Field Sample Plan.

GPRA. Government Performance Results Act.

HQ. Headquarters.
HRO. Human Resources Office.

IAG. Interagency Agreement.
IRM. Information Resources Management.

LP. Laboratory Program.

MSR. Management System Review.

NERL-CIN. National Exposure Research Laboratory, Cincinnati.
NPDES. National Pollution Discharge Elimination System.

OEI. Office of Environmental Information.

PE. Performance Evaluation.
PES. Performance Evaluation Samples.
PMD. Policy and Management Division.
PO. Project Officer.
PRP. Potentially Responsible Party.

QA. Quality Assurance.
QA/QC. Quality Assurance/Quality Control.
QAARWP. Quality Assurance Annual Report and Work Plan.
QAO. Quality Assurance Office.
QAPjP. Quality Assurance Project Plan.
QAPrP. Quality Assurance Program Plan
QMP. Quality Management Plan.
QC. Quality Control.
QS. Quality Staff.

RA. Regional Administrator.
RAC. Remedial Action contract.
RMO. Records Management Officer.
RPM Remedial Project Manager
RQAM.. Regional Quality Assurance Manager.
RS&T. Regional Science and Technology.

SAP. Sampling and Analysis Plan.
SESS. Superfund Enforcement Support Services.
SIRMO. Senior Information Resources Management Officer.
SOP. Standard Operating Procedure.
STARS. Strategic Targeted Activities for Results System.
START. Superfund Technical Assessment & Response Team.
STORET. Storage and Retrieval (database).

TSA. Technical Systems Audit.

VOC. Volatile Organic Compounds.

WAM. Work Assignment Manager.
WP. Work Plan.